Is PrEP Positive?

A study suggests that HIV meds can prevent infection. But questions remain about treatment as prevention.

February 3, 2011 By Mark Leydorf

Would you take an antiretroviral pill daily to prevent HIV? I posed this question to my volleyball team, a group of HIV-negative twenty- and thirtysomething gay men in New York City. Most said no. “The drugs are hard on you and super expensive,” said one. “Safe sex works,” another added. Later, walking up Eighth Avenue to the subway, a third teammate demurred. “Hell yes I would take it. It would be worth it, just to have the freedom from worrying,” he said. “And, I’m sorry, but condoms are just, like, the worst thing ever.” I reminded him that PrEP—pre-exposure prophylaxis—demands taking daily medication without missing a dose. “I would totally do it,” he said. “I would carry the pills around.” And the expense? “Bring it on.”

There is still no cure for AIDS, but this past November, data from PrEP research raised hope of a possible new prevention tool. *Time* magazine declared PrEP the “top medical breakthrough” of 2010 after results of the iPrEx (pre-exposure prophylaxis initiative) study showed that Truvada (tenofovir plus emtricitabine), if taken every day, can cut HIV transmission risk by 73 percent. Truvada (which, with Sustiva/efavirenz makes up the HIV combo pill Atripla) was chosen for its low toxicity and relatively few side effects, and after it showed good results in studies in mice. More PrEP trials have enrolled some 20,000 volunteers around the world; outcomes are expected over the next two years.

But who will benefit? Perhaps people like Ambrose Viparatin and Richard Gran-ville of Sierra Vista, Arizona, who have been lovers for 15 years. Viparatin, 50, has had HIV since 1983; Granville, 76, remains negative. Over the years, their sexual relationship has successfully shielded Granville from HIV. “After a decade and a half, you learn which buttons to push for each other, so our sex life is very good, if a bit limited on spontaneity. Luckily, I have grown up enough to recognize that the grass is not greener anywhere else,” Viparatin says. Granville adds, “Our sexual relationship satisfies us.”

Yet, this couple sees no benefit in pharmaceutical protection for the negative partner—even if it theoretically offers them the option of condom-less sex—given the expense and potential toxicity and side effects of HIV drugs. “That stuff is bad for you,” Granville says. In November, Eric Sawyer,

a cofounder of ACT UP and Housing Works who now works at UNAIDS, wrote on his POZ blog: “I have peripheral vascular disease, neuropathy, cardiovascular disease, arthritis; I at times had to take Imodium daily for diarrhea—all as a result of long-term [HIV med] use. Are there similar side effects from clean needles and condoms? I don’t think so!” While Sawyer isn’t talking specifically about Truvada’s side effects, you have to question the rationale for taking something that can *make* you ill in order to *prevent* getting ill. It would be like doctors prescribing chemo for life instead of advising smokers to give up cigarettes.

But while PrEP’s risks may not make sense for all, some people could benefit greatly from its potential. People in high-risk populations—IV drug users, sex workers, people who are not empowered in their relationships to demand safer sex, or simply single, sexually active people in large urban centers who want greater security—might see things differently. For them, the PrEP findings are potentially life changing.

Regardless of who might use it, PrEP’s overall results did not show a fail-safe benefit by any stretch. The global iPrEx research team, headquartered at the University of California at San Francisco, found that, on average, HIV-negative men taking Truvada were 44 percent less likely to contract the virus than men taking a placebo. The higher figure of 73 percent held true only for participants whose blood tests showed they’d faithfully taken every daily dose. It should also be noted that participants in the iPrEx study were counseled regularly to use condoms, and that many reported doing so. Kevin Fenton, MD, director of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, believes the results are promising enough that the agency will soon release suggested PrEP guidelines, which will include close medical supervision and adherence to other safe-sex practices.

Both the 73 and 44 percent figures still fall short of the nearly 100 percent protection from HIV that condoms are reputed to offer (in real life studies, condoms block infection at about 80 percent when used correctly).

In addition to PrEP’s lower efficacy rate, it is also far more expensive than the alternatives. Truvada costs $13,000 per year in the United States. It is extremely unlikely that insurance plans would ever cover it; and states, many of which are already unable to fund their AIDS Drug Assistance Programs (ADAP), are not likely to be able to cover the cost of PrEP.

Then there is the general uncertainty about the wisdom of giving potentially toxic medications to HIV-negative people. Nonetheless, Mark Harrington, founder and executive director of Treatment Action Group, says, “After several years of gloom on the vaccines and prevention front, I take [the Truvada findings] as very good news indeed.”

Jennifer Flynn, managing director of Health GAP, agrees, noting the implications for the concept of “treatment as prevention.” PrEP results, Flynn says, support the related idea of “providing treatment to HIV-positive individuals so they are less likely to infect others.” She is referring to the fact that treatment can lower a positive person’s viral load, cutting the risk of transmitting HIV. The acceptance of PrEP, she says, is “further evidence that achieving the goal of ’universal

access'—[defined as supplying drugs to 80 percent of those who need them]—would bring us close to actually controlling the spread of the virus." Flynn is not deterred by the possible costs. "I don't think anyone is envisioning prescribing Truvada to millions of people," she says. "The idea is [to give PrEP] to people at high risk." The principal obstacle, she says, is political. "It is absolutely feasible for governments to fund this. However, we are facing [scaled back] funding for AIDS treatment."

Harrington tempers his optimism (and Flynn's) with a dose of reality. "If confirmed, these results will not necessarily be easy to translate into practice," he says. "Who will pay for this prevention technology, given that HIV risks are not evenly distributed economically? What will be the effect of intermittent usage [of Truvada], which may be more convenient but also less [forgiving] than ongoing use? What will be the impact of the use of PrEP on emergence of drug resistance [in the larger population], given that it's the backbone of the most commonly used triple therapy in rich nations, Atripla?"

Finally, there is the concern that PrEP will encourage greater risk-taking.

Indeed, some suggest that people taking PrEP might become cavalier and toss condoms altogether, but in iPrEx, the opposite happened. Participants used condoms more often and had fewer partners. Who knows if the protective effect of PrEP would evaporate outside of the context of a study combining regular safe-sex counseling and free condoms?

Granville notes that PrEP's future relies on pill-takers as well as the pill itself: It might succeed "if [the pill] continues to work and if the people who should take it do so." Viparatin poses this question of adherence a bit more bluntly. "Want to have unsafe sex? Then perhaps you are willing to pay $1,000 a month for a greater chance of not getting infected. What if you decided to stop having unsafe sex? Would you still have to take the medication? For how long?" And on an individual level, would one missed dose put you at risk from one bareback episode? For now, it seems, education, counseling and promoting condom use must remain the backbone of HIV prevention.

Certainly condoms are unpopular. But are they, as my volleyball teammate says, the "worst thing ever"? Not to Viparatin. "Of course I miss [barebacking]," he says. "But it's not the unsafe sex I miss per se...it's the freedom and innocence of just 'doing it' any old way and not worrying about the consequences. But that was truly just an illusion anyway."

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http://beta.docker.poz.com/article/PrEP-Positive-HIV-19519-7655